DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 2, 2015

Cedic S.r.l.
% Roger Gray
VP, Quality and Regulatory
Donawa Lifescience Consulting S.r.l.
Piazza Albania, 10
Rome, 00153
Italy

Re: K150010
Trade/Device Name: Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIO
Dated: December 29, 2014
Received: January 2, 2015

Dear Roger Gray,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150010

Device Name

Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port

Indications for Use *(Describe)*

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is intended for connecting a male oral tip syringe or a male Luer slip tip syringe to an enteral giving set or enteral catheter with an ENFit medication port.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Device Name:	Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port
Type of 510(k) submission:	Traditional
Date of Submission:	29 December 2014
Manufacturer:	Cedic S.r.l. Biomedical Division Via Liberazione, 63/9 20068 Peschiera Borromeo (MI) Italy
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Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 rgray@donawa.com
FDA Product Code:	PIO
FDA Regulation Number:	876.5980
FDA Classification Name:	Enteral Specific Transition Connectors
Classification Panel:	Gastroenterology and Urology
Common Name:	Transition Connectors for Enteral Applications
FDA Classification:	Class II
FDA Identification:	Facilitates enteral specific connections between ENFit connectors and non 80369-1 compliant enteral connectors.

Device Description

The introduction of new connectors to devices and accessories for enteral feeding applications, in order to help avoid misconnections with devices intended for other clinical applications, has resulted in the short-term need to connectors that will allow devices with existing ('legacy') end connectors to be connected with newer devices having end connectors meeting the relevant requirements of the ISO/IEC 80369 series of standards.

Cedic is already marketing the Enteral ENFit Transition Connector for Medication Port in the US following FDA clearance, this device being for connecting a male oral tip syringe to an enteral giving set or enteral catheter with an ENFit medication port. This connector is available with and without end cap.

Cedic is now planning to introduce a very similar transition connector into the US market, this being the Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port, for connecting a male oral tip syringe or a male Luer slip tip syringe to an enteral giving set or enteral catheter with an ENFit medication port. This connector is also available with and without end cap.

The Cedic ENFit Transition Connectors are intended for prescription use only.

Indications for Use/Intended Use

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is intended for connecting a male oral tip syringe or a male Luer slip tip syringe to an enteral giving set or enteral catheter with an ENFit medication port.

Principle of operation, mechanism of action, and interaction with the patient:

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port operates by providing a means of interconnecting incompatible enteral feeding device end fittings together, so that patient enteral feeding can take place when 'new generation' end fittings in accordance with ISO/IEC 80369-3 need to be connected to previous designs of end fitting.

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port provides the mating components at each end of the connector that allow connection with the 'new' end fitting at one end of the connector, and connection with 'old' end fittings at the other.

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port will be used in combination with legally marketed enteral giving sets, enteral catheters, oral tip syringes or Luer slip tip syringes.

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is not intended to come into contact with the patient, but accidental contact may occur. The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port has a central fluid path through which feeding fluids flow during the feeding process.

Device Specification

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is for connecting a male oral tip syringe or a male Luer slip tip syringe to an enteral giving set or enteral catheter with an ENFit medication port. This connector is available with and without end cap.

The PGLock end of the connector is designed in compliance with ISO 80369-1:2010 and ISO/IEC AAMI/CN3 (PS):2014.

Manufacture

The Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is manufactured by injection molding from ABS HF 380. Where fitted, the end cap is colored with Remafin Violet PE43076356-ZT (2%). These materials are identical to those used for the selected predicate device.

Performance Data:

In relation to performance data for such ENFit Transition Connectors, according to the FDA publication 'Draft Guidance for Industry and Food and Drug Administration Staff: Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications', July 27, 2012:

> *"Adapters are used to connect enteral devices and provide additional connection points where misconnection events can occur. To mitigate misconnection via adapters, the FDA recommends that adapters be treated similarly to enteral connectors, as described in Section VI.A, B, and C within this guidance. This means that they should be made of rigid or semi-rigid materials, and mechanical testing should be performed according to recommendations described in AAMI/ANSI/ISO 80369-1, or an equivalent alternative, to demonstrate that adapters are specific and compatible for enteral applications only and are non-interconnectable with the connectors of non-enteral devices."*

The FDA draft guidance includes in Section VI. A, B and C the following recommendations:

A. Connector materials
"FDA recommends that enteral connectors be made of rigid or semi-rigid materials, as described in AAMI/ANSI/ISO 80369-1, Clause 4, with testing according to ASTM D747 or ASTM D790, or equivalent. Use of rigid or semi-rigid materials will reduce the likelihood of forced fits between flexible connectors that are not intended to connect with each other."

In this respect, the Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is made of the appropriate rigid or semi-rigid materials.

B. Mechanical testing of enteral connectors to assess incompatibility
"FDA recommends mechanical force testing of enteral connectors following AAMI/ANSI/ISO 80369-1, Clause 5.8, Annex B methods, or an equivalent alternative, to demonstrate that enteral connectors are non-interconnectable with connectors from other health care applications."

Bench tests have been carried out on samples of the Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port. The tests carried out include:

- Enteral connector misconnection assessment
- Human factors
- Fluid leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- Disconnection by unscrewing

The above tests include testing of the Luer part of the transition connector to demonstrate compliance with the relevant clauses of ISO 594-1.

C. Enteral connector risk assessment
"When an applicant submits a new 510(k) application, they should provide a risk assessment to demonstrate they have effectively mitigated the risk of misconnection with their new product. There should be objective evidence that risks have been reduced to acceptable levels according to ISO

14971:2007 or equivalent. For example, the applicant may provide evidence of selection of appropriate material (Section VI.A, above) and quantitative mechanical testing data to demonstrate that the proposed enteral connector has a reduced risk of forming stable attachments to connectors routing into non-enteral devices (Section VI.B, above).”

In this respect, this 510(k) submission includes a copy of the risk analysis for the subject transition connector.

Predicate device

The Predicate Device selected for comparison with the Subject Device is the Cedic Enteral ENFit Transition Connector for Medication Port

Sponsor: ..... Cedic Srl
510(k) Number: K140581
Clearance Date: ..... 17 October 2014
FDA Product Code: ..... PIO
Classification Name: ..... Enteral specific transition connectors
Regulation No: 876.5980

The Subject Device and the Predicate Device both share many identical or similar properties and features, and none of the differences have any significant effect on safety or effectiveness of the Subject Devices.

Conclusion:

Based on the information contained within this submission, it is concluded that the Cedic Oral/Luer Enteral ENFit Transition Connector for Medication Port is substantially equivalent to the identified predicate device already in interstate commerce within the USA.